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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Eric Hammill

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EXAMINER

STOKLOSA, JOSEPH A

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,843	Applicant(s) HAMMILL ET AL.	
	Examiner JOSEPH STOKLOSA	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 24 and 26-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-13 and 36 is/are allowed.
- 6) ☒ Claim(s) 1-10, 24, 26-35, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, filed 10/20/2008, with respect to Claim 1 have been fully considered and are persuasive. The rejection of 8/20/2008 has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 4, 9, 11-12, 24, 26-28, 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Langberg (US 5,246,438).

4. Langberg discloses an ablation catheter lead with a distal monitoring electrode, Fig. 5, 80, with a respective conductor, center wire 75. Langberg discloses a conductive sleeve in the form of an inner conductor 73 which is plated on the insulating plastic, with additional insulation 72, as seen in Fig. 5. Langberg discloses conductor 73 to be electrically isolated from all sensing and therapy electrodes through the use of a dielectric disk 78 (e.g. col. 9, line 55).

5. Examiner considers the inner conductor 73 to also inherently have a first impedance value in a first condition and a second impedance value in a second condition, where the second condition may be a fracture of the outer sleeve where there inner conductor's impedance value would be affected by the interaction with the

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implanted patient environment. While Langberg does not state a conductive sleeve has first and second impedance values in first and second conditions, respectively, and Applicant has not stated what constitutes a first or second impedance value and condition, it is known that all materials have a resistance (impedance) to electricity in any given condition and therefore it inherently has a first impedance before it is implanted (first condition) and a second impedance after implantation (second condition).

6. With respect to claim 11, Langberg discloses a conductive sleeve which Applicant has disclosed as the "means for detecting wear."

7. Claims 1-2, 4-9, 11-12, 24, 26-31, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster (US 5,569,220).

8. Webster discloses a cardiovascular electrode catheter with insulated concentric stainless steel braided meshes. Webster discloses a lead body 12, with distal electrodes 15, and copper conductor wires 16 (see Fig. 1). Examiner considers the stainless steel braided meshes to be conductive sleeves as stainless steel is conductive. Webster discloses the braided meshes are spaced apart by a layer of plastic insulation (e.g. Col. 3, line 34).

9. Examiner considers the braided meshes to also inherently have a first impedance value in a first condition and a second impedance value in a second condition, where the second condition may be a fracture of the outer sleeve where there braided meshes' impedance value would be affected by the interaction with the

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implanted patient environment. While Langberg does not state a conductive sleeve has first and second impedance values in first and second conditions, respectively, and Applicant has not stated what constitutes a first or second impedance value and condition, it is known that all materials have a resistance (impedance) to electricity in any given condition and therefore it inherently has a first impedance before it is implanted (first condition) and a second impedance after implantation (second condition).

10. With respect to claim 11, Webster discloses a conductive sleeve which Applicant has disclosed as the "means for detecting wear."

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 3, 5-8, 10, 13, 29-33, 35, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg as applied above.

14. Langberg fails to disclose a second conductive sleeve surrounding the first conductive sleeve, a second conductor, and a monitoring unit in electrical communication with at least one conductive sleeve as well as corresponding connectors for connecting the conductive sleeves to the monitoring device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Langberg with a second conductive sleeve surrounding the first conductive sleeve, a second conductor, and a monitoring unit in electrical communication with at least one conductive sleeve as well as corresponding connectors for connecting the conductive sleeves to the monitoring device for providing the predictable results to providing a tiered feedback of the effectiveness of the shielding braid and preventing leakage of current from affecting the patient detrimentally since a change in the impedance measurements of the metal braid conductive sleeves would indicate fracture which produces current leakage.

15. Claims 3, 10, 13, 32, 33, 35, and 37-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Webster as applied above.

16. Webster discloses the invention as claimed but fails to teach a monitoring unit in electrical communication with at least one conductive sleeve as well as corresponding connectors for connecting the conductive sleeves to the monitoring device. It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Webster with a monitoring unit in electrical communication with at least one conductive sleeve as well as corresponding connectors for connecting the conductive sleeves to the monitoring device for providing the predictable results to providing a tiered feedback of the effectiveness of the shielding braid and preventing leakage of current from affecting the patient detrimentally since a change in the impedance measurements of the metal braid conductive sleeves would indicate fracture which produces current leakage.

Allowable Subject Matter

17. Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. Applicant's amendment, filed 1/7/2008 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

Joseph Stoklosa
Examiner
Art Unit 3762

/Joseph Stoklosa/
Examiner, Art Unit 3762
11/10/2008